

Appl. No.: 09/764,149

June 6, 2003

REPLY MADE IN CONNECTION WITH RCE FILING

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This listing of claims will replace all prior versions, and listings, of claims in the application:

LISTING OF CLAIMS:

Claims 1-129 (Canceled)

130. **(newly added)** A male contraceptive composition in a form for administration by non-oral means comprising an effective amount of a norethisterone derivative possessing both androgenic and estrogenic properties, wherein the effective amount is such that effective levels of the norethisterone derivative are maintained in the circulation for not less than 4 weeks.

131. **(newly added)** The composition according to claim 130, wherein the effective amount is such that effective levels of the norethisterone derivative are maintained in the circulation for not less than 5 weeks.

132. **(newly added)** The composition according to claim 130, wherein the effective amount is such that effective levels of the norethisterone derivative are maintained in the circulation for not less than 6 weeks.

133. **(newly added)** The composition to claim 130, wherein the effective amount of norethisterone derivative is a dose of between 100 and 500 mg for a 6-week administration.

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134. (newly added) The composition to claim 133, wherein the effective amount of norethisterone derivative is a dose of between 200 and 400 mg for a 6-week administration.

135. (newly added) The composition according to claim 130, wherein the effective amount of the norethisterone derivative provides a daily release of the norethisterone derivative ranging between 1 and 10 mg.

136. (newly added) The composition according to claim 130, wherein the norethisterone derivative is a norethisterone carboxylic ester.

137. (newly added) The composition according to claim 136, wherein the norethisterone carboxylic ester is an acetate ester or an enanthate ester.

138. (newly added) The composition according to claim 137, wherein the norethisterone carboxylic ester is norethisterone enanthate.

139. (newly added) The composition according to claim 130, further comprising an androgen.

140. (newly added) The composition according to claim 139, wherein the androgen is a testosterone ester.

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141. **(newly added)** The composition according to claim 140, wherein the testosterone ester is selected from the group consisting of testosterone propionate, testosterone undecanoate, testosterone enanthate, testosterone cypionate and testosterone buciclate.

142. **(newly added)** The composition according to claim 141, wherein the testosterone ester is testosterone undecanoate.

143. **(newly added)** The composition according to claim 140, wherein the dose of the testosterone ester provides a daily release of testosterone in an amount between 5 and 35 mg.

144. **(newly added)** The composition according to claim 143, wherein the dose of the testosterone ester provides a daily release of testosterone in an amount between 15 and 30 mg.

145. **(newly added)** The composition according to claim 140, wherein the dose of the testosterone ester provides an amount of testosterone ranging between 500 and 1200 mg for a 6-week administration.

146. **(newly added)** The composition according to claim 142, wherein the effective amount of testosterone undecanoate is between 800 and 1500 mg for a 6-week administration.

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147. **(newly added)** The composition according to claim 146, wherein the effective amount of testosterone undecanoate is 1000 mg for a 6-week administration.

148. **(newly added)** The composition according to claim 130, wherein said administration by non-oral means is by intramuscular injection, intravenous injection, subcutaneous implant, subcutaneous injection or transdermal preparation.

149. **(newly added)** The composition according to claim 148, wherein said administration by non-oral means is by intramuscular injection, subcutaneous implant or transdermal patch.

150. **(newly added)** The composition according to claim 149 in a form for intramuscular injection.

151. **(newly added)** A kit comprising unit dosage forms in a form for administration by non-oral means comprising:

a norethisterone derivative possessing both androgenic and estrogenic properties in an effective amount such that effective levels of the norethisterone derivative are maintained in the circulation for not less than 4 weeks, and

an androgen,

wherein said norethisterone derivative and said androgen are in separate dosage units.

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152. **(newly added)** The kit according to claim 151, wherein the effective amount of the norethisterone derivative is such that effective levels of the norethisterone derivative are maintained in the circulation for not less than 5 weeks.

153. **(newly added)** The kit according to claim 151, wherein the effective amount of norethisterone derivative provides a dose of between 100 and 500 mg for a 6-week administration.

154. **(newly added)** The kit according to claim 151, wherein the effective amount of the norethisterone derivative provides a daily release of the norethisterone derivative of between 1 and 10 mg.

155. **(newly added)** The kit according to claim 151, wherein the androgen is a testosterone ester.

156. **(newly added)** The kit according to claim 155, wherein the testosterone ester is selected from the group consisting of testosterone propionate, testosterone undecanoate, testosterone enanthate, testosterone cypionate and testosterone buciclate.

157. **(newly added)** The kit according to claim 156, wherein the testosterone ester is testosterone undecanoate.

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158. **(newly added)** The kit according to claim 155, wherein the dose of the testosterone ester provides a dose of testosterone ranging between 500 and 1200 mg for a 6-week administration.

159. **(newly added)** The kit according to claim 151, wherein said administration by non-oral means is by intramuscular injection, intravenous injection, subcutaneous implant, subcutaneous injection or transdermal preparations.

160. **(newly added)** The kit according to claim 159, wherein said administration by non-oral means is by intramuscular injection, subcutaneous implant or transdermal preparations.

161. **(newly added)** The kit according to claim 160, wherein said dosage units are in a form for intramuscular injection.

162. **(newly added)** A method of providing male contraception comprising administering by non-oral means to a male individual an effective amount a norethisterone derivative, possessing both androgenic and estrogenic properties, said administration being in intervals of not less than 4 weeks.

163. **(newly added)** The method according to claim 162, wherein the administration is in intervals of not less than 5 weeks.

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164. **(newly added)** The method according to claim 162, wherein the administration is in intervals of not less than 6 weeks.

165. **(newly added)** The method according to claim 162, wherein the dose of norethisterone derivative is between 100 and 500 mg for a 6-week administration.

166. **(newly added)** The method according to claim 165, wherein the dose of norethisterone derivative is between 200 and 400 mg for a 6-week administration.

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167. **(newly added)** The method according to claim 162, wherein the norethisterone derivative dose provides a daily release of a norethisterone derivative in an amount between 1 and 10 mg.

168. **(newly added)** The method according to claim 162, wherein the norethisterone derivative is a norethisterone carboxylic ester.

169. **(newly added)** The method according to claim 168, wherein the norethisterone carboxylic ester is an acetate ester and/or an enanthate ester.

170. **(newly added)** The method according to claim 169, wherein the norethisterone carboxylic ester is norethisterone enanthate.

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171. **(newly added)** The method according to claim 162, further comprising administering an androgen by non-oral means.

172. **(newly added)** The method according to claim 171, wherein the amount of said norethisterone derivative and said androgen provides effective levels of said norethisterone derivative and said androgen in the circulation for not less than 4 weeks.

173. **(newly added)** The method according to claim 172, wherein the effective levels in the circulation are sustained for not less than 5 weeks.

174. **(newly added)** The method according to claim 172, wherein the effective levels in the circulation are sustained for not less than 6 weeks.

175. **(newly added)** The method according to claim 171, wherein the androgen is a testosterone ester.

176. **(newly added)** The method according to claim 175, wherein the testosterone ester is selected from the group consisting of testosterone propionate, testosterone undecanoate, testosterone enanthate, testosterone cypionate and testosterone buciclate.

177. **(newly added)** The method according to claim 176, wherein the testosterone ester is testosterone undecanoate.

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178. **(newly added)** The method according to claim 175, wherein the dose of the testosterone ester provides a daily release of testosterone in amounts ranging between 5 and 35 mg.

179. **(newly added)** The method according to claim 175, wherein the dose of the testosterone ester provides a daily release of testosterone in amounts ranging between 15 and 30 mg.

180. **(newly added)** The method according to claim 177, wherein the dose of the testosterone ester provides a dose of testosterone ranging between 500 and 1200 mg for a 6-week administration.

181. **(newly added)** The method according to claim 180, wherein the dose of testosterone undecanoate ranges between 800 and 1500 mg for a 6-week administration.

182. **(newly added)** The method according to claim 181, wherein testosterone undecanoate is in a dose of 1000 mg for a 6-week administration.

183. **(newly added)** The method according to claim 162, wherein said norethisterone derivative is administered by intramuscular injection, intravenous injection, subcutaneous implantation, subcutaneous injection or through a transdermal preparation.

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184. **(newly added)** The method according to claim 162, wherein said androgen is administered by intramuscular injection, intravenous injection, subcutaneous implantation, subcutaneous injection or through a transdermal preparation.

185. **(newly added)** The method according to claim 162, wherein said norethisterone derivative and androgen are administered by intramuscular injection, subcutaneous implant or through a transdermal preparation.
